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Mr. Chairman and distinguished members of the House Government Reform Committee, my name is Dr. Robert Stroube. I am the State Health Commissioner for the Virginia Department of Health (VDH), and I am honored to be testifying before you today. I would like to thank the Chair and the subcommittee members for convening this hearing.

As State Health Commissioner I serve as the principal advisor to Virginia Governor Mark Warner, Virginia Secretary of Health and Human Resources Jane Woods and the Virginia General Assembly on a wide range of public health issues. I earned a Doctor of Medicine degree from the Medical College of Virginia, a Masters in Public Health from Johns Hopkins University, and an undergraduate degree from the College of William and Mary. I am a specialist in preventive medicine and certified by the American Board of Preventive Medicine.

Since news broke that British regulators suspended the license of flu vaccine manufacturer Chiron last October, state and local public health officials have been working to ensure the best use of available doses of vaccine. Initially that meant prioritizing vaccine availability to individuals at greatest risk for developing serious complications from the flu. More recently it has included responsible relaxation of vaccine recommendations to include individuals outside of the original high-risk groups to ensure use of remaining doses.

When news reports disclosed that Chiron had lost its licensing privileges, VDH stood to lose 90 percent of its total flu vaccine order -- approximately 110,000 doses. The loss of Chiron vaccine, however, did not significantly impact the 115,000 doses of flu vaccine ordered from Aventis for children enrolled in the Vaccines for Children (VFC) program. This program serves uninsured and underinsured children, Native American children, and those on Medicaid.

The health department provides a very small proportion of the flu vaccine that is typically provided to the public. During a typical year the health department provides about 70,000 doses of flu vaccine. Most vaccine is provided by the private sector.

In response to the vaccine shortage, VDH immediately implemented the Advisory Committee on Immunization Practices (ACIP) recommendation regarding the prioritization of all injectable flu vaccine. In addition, every effort was made to educate the medical community about the recommendations and urge compliance. A message was sent out to health care providers through Virginia's Health Alert Network. VDH issued a statewide press release, including information about the vaccine shortage and encouraged prioritization of available flu vaccine. State and local health departments received hundreds of phone calls from concerned citizens and numerous media interviews were conducted. VDH diligently worked to provide the best information available, during the developing situation.

From the beginning of the flu vaccine shortage, the CDC worked closely with Aventis to allocate and distribute all remaining doses of vaccine. In the weeks and months following, VDH

received four shipments of redistributed vaccine, with each targeting a different high-risk population.

In November, VDH received 80,000 doses of flu vaccine to distribute to its 119 local health departments. The decision was made to distribute the vaccine to each health district based on population. Local health districts developed flu vaccine distribution plans tailored to best meet the needs of high-risk populations in each community.

As the first doses of flu vaccine from the CDC allocations began to arrive in late October and early November, health districts worked to implement their vaccine distribution plans. Individuals not included in the priority groups were asked to defer vaccination in order to preserve limited doses of vaccine. The live nasal spray (Flu mist) was encouraged for healthy people of ages 5–49 years who were not pregnant.

Another allocation of approximately 77,000 doses was sent in mid-November primarily to long-term care facilities across the state. This enabled nursing homes and assisted living facilities to vaccinate their vulnerable residents. At this time the VFC program also received the remainder of its order.

Also in mid- November, Virginia began to request vaccine via CDC's Web-based secure data network. The network allowed state public health officials the ability to order flu vaccine on behalf of private health care providers directly from CDC. As a result, VDH was able to distribute approximately 98,000 doses to Virginia's private physicians and pharmacists.

By the end of November, CDC and Aventis had redistributed a total of 255,000 doses to VDH. VDH sought to reach as many high-risk populations as possible by providing flu vaccine to health departments, long-term care facilities, and private physician offices throughout the state.

Throughout November and December, VDH continued to recommend flu vaccine to individuals in the priority groups and publicize vaccine availability via press releases and media interviews; however, demand in many areas had begun to diminish significantly.

By late December it appeared that the majority of high-risk persons in most parts of Virginia who wished to be vaccinated had obtained vaccine. According to a December study by the CDC's Behavior Risk Factor Surveillance System, 63 percent of people 65 and older and 46 percent of chronically-ill adults received an influenza vaccination in October or November. However, more than half of adults at increased risk did not try to get the influenza vaccine. In Virginia, as in other states, it appears many high-risk individuals self-deferred from vaccination due to the vaccine shortage.

A late December inventory survey revealed an available supply of flu vaccine in many parts of the state. To help ensure that available flu vaccine did not go to waste, I authorized the expansion of the vaccine recommendations to include individuals aged 50 to 64 and household contacts of those in high-risk categories to take effect on
January 10, 2005. This expansion was in agreement with revised ACIP recommendations. Even with the expansion there was little interest by private providers in placing an order from

Virginia's fourth allocation of vaccine, approximately 55,000. By the time orders were due to the CDC, on January 13, little over 30,000 doses had been requested. A survey conducted on January 20 revealed that 35,000 doses of VFC vaccine were still sitting unused, available for distribution.

In late January, the CDC began to support the expansion of vaccine eligibility for states and localities with ample supplies. On January 26, I authorized district health directors to lift flu vaccine restrictions in their localities if they felt the demand for vaccination within priority groups had been met. Administration of flu vaccine to members of the general population would allow remaining doses of vaccine to be used judiciously to provide protection against influenza for as many people as possible.

As of January 27, CDC made VFC influenza vaccine available to health departments for non-VFC children or adults in localities where the demand for influenza vaccine among eligible children had likely been met. VDH is working closely with private physicians, advising them of the opportunity to purchase additional vaccine directly from Aventis with a provision that would allow for the return of unused vaccine for a full refund. VDH has also notified all private providers enrolled in the VFC program that they may contact their local health department for the transfer of their unused stock of VFC influenza vaccine. Local health departments have been authorized to redistribute transferred vaccine to other public facilities, free clinics, community health centers or private non-profit facilities.

Despite VDH's effective response to the unexpected shortage of flu vaccine, the continuing problems with influenza vaccine availability pose great difficulties for our state in planning for

the next flu season. We do not know what the availability of flu vaccine will be next season. Will there be enough for everyone or high-risk groups only? If there is a continuing shortage what will be the role of state and local health departments in vaccine distribution? Will things be done as in previous years with the private sector handling most of the distribution or do we need to build on this year's ad hoc system using state and local health departments to coordinate distribution?

Historically, in Virginia, the private sector has administered the great majority of flu vaccine. This season's crisis led to much greater government intervention in the distribution and administration of vaccine. Will the private sector return to their former level of involvement? In Virginia, the trend has been for large businesses such as Wal-Mart, drug chains, and grocery store chains to provide much of the vaccine. Long lines and traffic congestion and unfavorable publicity this season may make them wary of continued participation. Private health care providers have been less active in flu administration and the shortage may make them less willing to deliver vaccine in their practices.

The public has received many mixed messages about flu vaccine as the crisis developed. There were public campaigns to urge widespread immunization, then campaigns to ask people not at high-risk to defer vaccination. There was a severe shortage of vaccine, and then there was a surplus of vaccine with changing recommendations. Fortunately, we have had a light flu season to date. However, this confusion had led to the belief in some of the public that there was less vaccine, but less flu so maybe individuals really didn't need to be vaccinated in the first place. We need to have a good idea about next season's vaccine availability as soon as possible to craft our campaign strategies.

Throughout this crisis our state and local health departments have devoted incredible amounts of time to try to get our most vulnerable citizens vaccinated. The U.S. Centers of Disease Control and Prevention has provided national leadership in a difficult and changing environment and has worked very closely with us to meet the needs of our citizens and we are appreciative of their efforts. The ultimate solution is the development of an adequate, secure, and stable supply of vaccine as we have stated in our previous testimony before your committee. We appreciate the amount of time and effort your committee has devoted to these important issues. Thank you for the opportunity to speak with you today. I would be pleased to answer any questions you may have.